

K981612 ALL SILICONE FOLEY CATHETER, TWO-WAY FOLEY CATHETER, THREE-WAY FOLEY CATHETER, TWO-WAY RADIOPAQUE FOLEY CATHETERJul 8, 1998
63 days to decisionK981612 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k981612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 6, 1998
Decision date	Jul 8, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rochester Medical Corp.
Location	Rochester, MN, US
Contact	MARY WILEN
510(k) history	13 submissions · 13 cleared · 1990-2013

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